

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert Falotico, et al. Confirmation No.: 3367
Appln. No. : 10/780,596
Filed : February 18, 2004
Title : LOCAL VASCULAR DELIVERY OF CLADRIBINE IN
COMBINATION WITH RAPAMYCIN TO PREVENT RESTENOSIS
FOLLOWING VASCULAR INJURY
Art Unit : 3738
Examiner : Pellegrino, Brian E.

**I hereby certify that this correspondence is being transmitted via
The Office electronic filing system in accordance with 37 CFR 1.6(a)(4)**

**7/05/07
(Date of Transmission)**

**Carl J. Evens
(Name of applicant, assignee, or Registered Representative)**

/Carl J. Evens/

**7/05/07
(Date of Signature)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**COMMUNICATION
(Petition under 1.181)**

Dear Sir:

This Communication and Petition is in response to a Notice of Abandonment mailed July 3, 2007. The Notice incorrectly asserts a number of facts. Firstly, a complete and proper response to the Office Action mailed October 11, 2006 was filed on January 11, 2007, a copy of which is attached hereto. In addition, a copy of the electronic filing receipt indicating that the response was received is also attached. Secondly, a phone call was received by Applicants' Attorney and Applicants' Attorney informed the Examiner that a correct and proper response was filed in the correctly identified application. Accordingly, Applicants respectfully request that the above-referenced application be reinstated to Active status and acted upon.

Serial No. 10/780,596

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Account No. 10-0750/CRD5065/CJE due as a result of this Request.

Respectfully submitted,

/Carl J. Evens/

By: _____
Carl J. Evens
Reg. No. 33,874

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One Johnson & Johnson Plaza
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Dated: July 5, 2007

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P.O. Box 1450
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AMENDMENT

Dear Sir:

In response to the Office Action mailed October 11, 2006 Applicants respectfully request that the referenced patent application be amended as follows:

Amendments to the Claims are reflected in the listing of claims, which begin on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

6. (Currently Amended) The medical device according to claim 51, wherein the first polymeric material comprises a fluoropolymer.

7. (Currently Amended) The medical device according to claim 51, wherein the second polymeric material comprises an acrylic.

8. (Cancelled) A medical device comprising:
an implantable structure; and
a combination of rapamycin and cladribine, in therapeutic dosages, releasably affixed to the implantable structure for the treatment of restenosis following vascular injury.

9. (Cancelled) The medical device according to claim 8, wherein the implantable structure comprises a stent.

10. (Cancelled) The medical device according to claim 8, wherein the implantable structure comprises a stent-graft.

11. (Cancelled) The medical device according to claim 8, wherein the implantable structure comprises an anastomosis device.

12. (Cancelled) The medical device according to claim 8, further comprising a polymeric coating, the combination of rapamycin and cladribine being incorporated into the polymeric coating.

13. (Cancelled) A method for treating restenosis comprising the local administration of a therapeutic dose of a combination of rapamycin and cladribine.

14. (Cancelled) A method for treating restenosis comprising the

administration of a therapeutic dose of a combination of rapamycin and cladribine.

Amendments to the Claims:

REMARKS/ARGUMENTS

In response to the Office Action mailed October 11, 2006, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, Claims 1, 6 and 7 are amended, no claims have been added, and Claims 5 and 8-14 have been cancelled so that Claims 1-4 and 6-7 are currently pending. No new matter has been introduced.

Claims 1-5 and 8-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 01/87372 to Kopia et al. in view of EP 1127582 to Kopia et al. Claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 01/87372 in view of EP 1127582. These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re* Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re* Royka, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in

a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

In WO 01/87372 Kopia et al. discloses a combination of an anti-inflammatory such as dexamethasone and an antiproliferative such as cladribine and rapamycin. Kopia et al. does not disclose a combination of cladribine and rapamycin. In EO 1 127 582 Kopia et al. discloses the use of cladribine to prevent restenosis. Once again, the combination is not suggested. In addition, neither of the references, whether taken alone or in combination discloses the use of dissimilar polymers to create a chemical and physical barrier.

In addition, assuming that all of the elements are present, Applicants respectfully submit that the Examiner is using impermissible hindsight in combining the references. As stated above, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In *re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Furthermore, recently the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") restated the legal test applicable to rejections under 35 U.S.C. 103(a) (In *re Rouffet*, 47 USPQ2d 1453 (Fed. Cir., July 15, 1998)). The Court stated: [V]irtually all [inventions] are combinations of old elements. Therefore an Examiner may often find every element of a claimed invention in the prior art. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to

combine the references that create the case of obviousness. The Board [of Appeals] did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the field of the art. If such a rote indication could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct the suggestion to combine requirements stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness. *In re Rouffet*, 47 USPQ2d 1457-58 (Fed. Cir., July 15, 1998) (citations omitted, emphasis added). More recently, the Federal Circuit again dealt with what is required to show a motivation to combine references under 35 U.S.C. 103(a). In this case the court reversed the decision of the Board of appeals stating:

[R]ather than pointing to specific information in Holiday or Shapiro that suggest the combination..., the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other-in combination with each other... described all of the limitations of the pending claims. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the ... references, nor does the Board make specific-or even inferential-findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any factual findings that might serve to support a proper obviousness analysis. *In re Dembiczak*, 50 USPQ2d 1614, 1618 (Fed. Cir., April 28, 1999) (citations omitted, emphasis added).

Thus, from both *In re Rouffet* and *In re Dembiczak* it is clear that the Federal Circuit requires a specific identification of a suggestion, motivation, or teaching why one of ordinary skill in the art would have been motivated to select the references and combine them or an identification of the level of skill in the art at the time of the invention which would make him likely to combine his skill with the teachings of the art to come up with the invention.

This the Examiner has not done. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

Respectfully submitted,

/Carl J. Evens/

By: _____
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Dated: January 11, 2007

Electronic Acknowledgement Receipt

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Application Number:	10780596
International Application Number:	
Confirmation Number:	3367
Title of Invention:	Local vascular delivery of cladribine in combination with rapamycin to prevent restenosis following vascular injury
First Named Inventor/Applicant Name:	Robert Falotico
Customer Number:	27777
Filer:	Carl J. Evens/Frances Levine
Filer Authorized By:	Carl J. Evens
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Amendment - After Non-Final Rejection	Amendment11107CRD5104.pdf	293987	no	7

Warnings: